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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA, et al. *ex rel.* BROOKS WALLACE, ROBERT FARLEY, and MANUEL FUENTES, Plaintiffs, v. EXACTECH, INC., Defendant.	CIVIL ACTION NUMBER 2:18-CV-01010-LSC Opposed

MEMORANDUM OF LAW
IN SUPPORT OF EXACTECH, INC.'S MOTION FOR SUMMARY JUDGMENT

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Defendant Exactech, Inc. respectfully requests that the Court grant summary judgment in its favor on all causes of action in Relators' Amended Complaint.

INTRODUCTION

Relators' case hinges on their allegation that a defect in Exactech's Optetrak Finned Tibial Tray requires surgeons to perform a revision surgery and replace the device after it prematurely loosens from the tibia at an exceptionally high rate of 30–35%. The undisputed material facts show that the true percentage of revision surgeries due to tibial loosening is less than 1%. That alone is fatal to their case.

Relators' legal claims rely on an unfounded design-defect theory that Exactech's Optetrak Finned Tibial Tray ("Optetrak Finned Tibial Tray" or the "Device") is defective due to design changes Exactech made around 2008. But there were no significant design changes in that time period. And Relators cannot point to any evidence that the alleged "defect" resulted in premature aseptic tibial loosening[1] of the Device at a rate of "30–35% in the first three years" following implantation, or anything remotely approximating that rate.

Consistent with the actual aggregate failure rate of less than 1%, Relators have discovered evidence of only a handful of isolated instances where a surgeon experienced elevated tibial loosening problems with the Device. Relators have

[1] The term "loosening" refers to the failure of the bond between the bone and the implant, which can occur for a myriad of reasons, such as trauma or infection. "Aseptic loosening" refers to instances of loosening that occur without any specifically identified cause of the loosening. All refences to loosening in this Brief refer to aseptic loosening, unless specifically noted otherwise.

identified only three U.S.-based surgeons from whom they have obtained evidence of higher-than-expected rates of tibial loosening.[2] Two of those surgeons' issues—which they both testified occurred far below the rate Relators allege—happened well before 2008, when Relators contend that Exactech modified the design and introduced the defect. That leaves one surgeon—out of over 500—to substantiate Relators' case. An actual defect in the Device, however, would have manifested in widespread performance issues in more than just a single surgeon's patients.

Exactech vigorously denies that the Device is defective, and the evidence does not support Relators' theory. But assuming Relators attempt to dispute that (presumably based on their experts' opinions[3]), they still face an insurmountable problem: there is no competent evidence of a nexus between the Device's design and any particular failed primary total knee arthroplasty (TKA).[4] Isolated instances of tibial loosening are normal in TKA, and the actual rate here, which is below expectations for similar products, cannot support an elevated overall failure rate, which would be necessary but not sufficient to support a fraud claim. For Relators to prove Exactech perpetrated a fraud on the government by selling a defective Device to hospitals and surgeons who implanted them in Medicare and Medicaid patients in violation of the False Claims Act (FCA), they would need evidence that

[2] Two clusters of surgeons outside the U.S. experienced problems after making obvious mistakes in their procedures—such as using another manufacturer's instruments to implant the Device.
[3] Exactech has not yet had the opportunity to depose Relators' experts to test their opinions.
[4] The terms total knee arthroplasty (TKA) and total knee replacement (TKR) are interchangeable.

the Device failed in specific cases, and that such cases were so widespread that the Device should have been removed from the market. Far from developing such evidence, Relators have developed only an extremely attenuated casual chain that requires huge, legally impermissible, leaps of faith at every step.

BACKGROUND

The FDA cleared the Optetrak Finned Tibial Tray in 1994. Twenty-eight years later, it remains on the market, and Exactech continues to manufacture and sell the Device. Despite extensive peer-reviewed literature addressing its safety and effectiveness, along with the approximately 500 surgeons in the U.S. who never reported any problems, Relators guessed that the Device fails at a rate of up to 35% based on scattered anecdotes primarily involving a single surgeon, Dr. David Lemak. In reality, the known revision rate is less than 1%.

Calculating the true revision rate is a simple—the number of reported failures divided by the total number of knees sold. Exactech provided Relators those data, yet Relators testified that they essentially guessed at the revision rate:

- Relator Fuentes testified that he had conversations with just three foreign physicians—one in Guatemala, one in Argentina, and one in Italy—from which he extrapolated an alleged revision rate for U.S.-based procedures.

- Relator Farley testified that he "can't calculate [the alleged revision rate] because I don't know. . . . I mean, to me it's the studies [that] show what the failure rates are." When asked if he can identify the total number of revision surgeries involving the Device, he testified, "I don't believe Exactech would give us that information." Finally, he testified he did not independently calculate a revision rate, he "Just [uses] what Manny [Fuentes] tells me."

- Relator Wallace testified that the revision rate "probably would have come from Manny [Fuentes]." And, in regard to Dr. Lemak's alleged revision rate of 25%, he stated, "I don't know if we did [the calculation] originally first. I don't know if our attorneys did it and put it into the complaint."

Relators have no evidence to support their alleged extraordinary revision rate.[5]

Exactech expects Relators to argue that Exactech failed to report certain revision surgeries, so the data is underinclusive. But Relators have no evidence of this either. Specific FDA regulations, not Relators' subjective beliefs, govern Exactech's reporting obligations, and Relators have not identified any instances of tibial loosening that Exactech was obligated, but failed, to report.

Despite Relators' allegation that at least 20 surgeons had problems, the evidence makes clear that Relators' case relies on the individualized experiences of just three surgeons out of 514 users: Drs. Moody, Hutchins, and Lemak. It is implausible that the allegedly defective Device—with an alleged 30–35% revision rate—affected only those three surgeons. If the Device were defective, failures would be distributed across the entire population of users. In truth, the source of the problems those physicians experienced is related to technique—not the Device.

Two of those surgeons (Drs. Moody and Hutchins) had loosening problems well before 2008, contrary to Relators' proposed timeline. And both testified that

[5] Exactech maintains that Relators failed to satisfy the heighted-pleading standard in Rule 9(b) of the Federal Rules of Civil Procedure, and further requests that the Court dismiss all counts for failure to satisfy Rule 9(b). *See U.S. ex rel. Schwartz v. Coastal Healthcare Grp., Inc.*, 232 F.3d 902 (10th Cir. 2000) ("[A] Rule 9(b) deficiency may be resolved by summary judgment.").

their revision rates were around 7%, a far cry from the failure rate Relators allege.

Only a single surgeon—Dr. Lemak—had higher-than-normal rates of tibial loosening after 2008. Relators insist that Dr. Lemak's failures alone are evidence of a defect. The evidence does not show that, and common sense dictates otherwise. Relators have not developed any admissible evidence to support a higher-than-expecting revision rate.[6] Exactech attempted on six separate occasions to obtain Dr. Lemak's testimony, but he evaded service of Exactech's subpoenas.

Dr. Lemak notwithstanding, there is no admissible evidence of a widespread issue with the Device. To the contrary, the product is so successful that Dr. Roy William Petty and his wife, Betty Petty, co-founders of Exactech, chose the Device for Ms. Petty's first TKA. That surgery took place 19 years ago. Ms. Petty has never had an issue with the Device, despite continuing to live an active lifestyle (downhill skiing until retiring from the sport in 2019). The Device remains FDA approved and on the market to this day, and Exactech continues to manufacture it.[7]

It is well established that a false claim for payment is necessary to prove an

[6] Relators obtained a transcribed statement from Dr. Lemak six days before the close of fact discovery. SF ¶ 58. But they have withheld that responsive statement on the basis of the work-product doctrine, and thus cannot use it as evidence. *See* Fed. R. Civ. P. 37(c)(1)(C); 37(b)(2)(A)(ii) (a court may prohibit "the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence"); *see also Grant v. Ent. Cruises & Spirit Cruises, LLC*, 767 F. App'x 15, 16 (D.C. Cir. 2019) (affirming decision to preclude testimony because of plaintiff's failure to comply with Fed. R. Civ. P. 26).

[7] The Optetrak Logic Finned Tibial Tray succeeded as the next generation of the Device around 2009. SF ¶¶ 3–5. The changes to the design (making the surface coating finish rougher) are not material to this dispute (Relators' allege the defect results in part from a too smooth coating finish). SF ¶ 4. The Logic Finned Tibial Tray continues to be manufactured today. SF ¶ 14.

FCA violation. Relators must have evidence of a claim presented to CMS *for a Device that actually failed as a result of a design defect*. They have none. Relators have not identified a single instance of a Device failure due to a design defect. The undisputed facts show the Device is safe, reliable, and successful, and Exactech respectfully requests that the Court grant summary judgment on all claims.

STATEMENT OF UNDISPUTED MATERIAL FACTS[8]

A. Exactech, Inc. background and Optetrak product history.

1. Founded in 1985, Exactech is based in Gainesville, Florida. Decl. of Exactech Rep., Ex. A, ¶ 3; Dep. of Dr. Roy William Petty, Ex. B, 57:22–23.

2. Exactech focuses on physician-oriented products. Each product line and implant system were developed in consultation with surgeons and surgeon-customers. Ex. A, ¶ 3. Exactech was founded by physicians, for physicians. *Id.*

3. Exactech has marketed two generations of Optetrak knee prostheses: the first-generation Classic and the current generation Logic. Ex. A, ¶ 5.

4. Exactech has marketed three tibial-tray designs for Optetrak systems: Finned (FDA-cleared in late 1994); Trapezoidal (FDA-cleared in early 1995); and a combination tray (FDA-cleared in 2010 and marketed as the Fit tray), which has both fins and a trapezoid-shaped stem. Ex. A, ¶ 5. The Optetrak Logic Finned Tibial Tray succeeded as the next generation of the Device around 2009. *Id.* ¶¶ 7–

[8] This Statement of Undisputed Material Facts is referred to as "SF" in this Brief.

8. The changes to the design (making the surface coating finish rougher) are not material to this dispute (Relators' allege the defect results in part from a too smooth coating finish). *Id.*, ¶ 8.

5. In approximately 2008 or 2009, Exactech began developing the "Fit" tray. Ex. A, ¶ 10. The primary driver for the Fit tray was to "reduce inventory" by combining the popular aspects of the Finned and Trapezoidal trays. Ex. B, 317:9–19; *see also* Ex. A, ¶ 10. Moreover, the development was market-driven: most of Exactech's competitors had combination trays, and Exactech wanted to be able to offer its own combination product to its clients. Ex. A, ¶ 10.[9] The Optetrak Classic has either the Finned or Trapezoidal tray, and all three tray designs are available with the Logic system. Ex. A, ¶ 10.

B. Optetrak Finned Tibial Tray's lineage.

6. Exactech's Optetrak TKR system, and the Optetrak Finned Tibial Tray in particular, was based on the revolutionary Insall-Burstein prosthesis, first introduced in 1978. Decl. of Dr. Raymond Robinson, Ex. C, ¶ 8; Ex. A, ¶ 5.

7. In designing the Optetrak system, Exactech entered into an agreement with the world-renowned Hospital for Special Surgery (HSS), Albert H. Burstein,

[9] Former Exactech CEO David Petty prepared an academic discussion paper for an executive leadership program he attended. The paper posits a scenario in which Exactech developed the Fit tray on an accelerated timeline. Relators did not examine Mr. Petty about the paper, and every witness that Relators did question about the paper testified that they disagreed that the Fit tray was developed in rapid fashion. *See* Ex. B, 402:4; Dep. of Luis Alvarez, Corporate Representative, Ex. X, 198:7–22; Dep. of Charlie Rye, Ex. Y, 57:22–23.

Ph.D., and his colleagues at HSS to help design the Optetrak system, including the Optetrak Finned Tibial Tray. Ex. C, ¶ 8; Ex. A, ¶ 5.

8. The Optetrak system incorporates the key features of the Insall-Burstein prosthesis design, and it also incorporates improvements informed by surgeon experience. Ex. C, ¶ 8; Ex. A, ¶ 5. Exactech was one of three companies to receive a license from HSS to design and market an Insall-Burstein prosthesis. *See* Deposition of Manuel Fuentes, Ex. D, 49:8–10; 59–6–15; Ex. C, ¶ 11; Ex. A, ¶ 5.

9. Most device manufactures sold finned trays at the same time Exactech sold the Optetrak Finned Tibial Tray. Ex. D, 65:2–6; Ex. C, ¶ 10; Ex. A, ¶ 5.

C. Optetrak Finned Tibial Tray's proven performance.

10. Exactech's Optetrak Finned Tibial Tray has never been recalled for safety reasons, nor has the FDA ever withdrawn clearance for the Device. Ex. A, ¶ 6; Deposition of David Petty, Ex. E, 385:13–386:8.[10]

11. The known revision rate for the Optetrak Finned Tibial Tray is 0.0983% from 2007 through March 2021. Exactech's Answer to Interrogatory No. 15 (Set One), Ex. F; Ex. A, ¶ 6.

12. Given its proven performance, Exactech continues to sell and

[10] To the extent Relators point to publicly available information about the ongoing recall of Exactech's knee products, initiated in February 2022, as evidence that they are not safe and effective, that recall concerns a polyurethane insert to the overall device and is entirely unrelated to the Optetrak Finned Tibial Tray component at issue in this case. *See* https://www.exac.com/medical-professionals/recall-information/.

manufacture the Optetrak Finned Tibial Tray to this day. *See* Exactech Sales-Data Spreadsheet, Ex. G; Ex. A, ¶ 7 (Ex. A, current picture of the manufacturing line).

13. From 1994 to the present, Exactech sold 58,763 Optetrak Finned Tibial Trays in the United States to 514 different surgeons. Ex. A, ¶ 7.

14. The estimated known revision rate for any TKR implant on the market is between 2% and 10%. *See* Ex. C, ¶ 13 (citing various scientific journals).

15. Dr. Petty and his wife, Betty Petty, co-founders of Exactech, chose the Optetrak Finned Tibial Tray for Ms. Petty's first TKA surgery. Ex. B, 445:14–450:8. That surgery took place 19 years ago. *Id.*, 450:1–8. Despite continuing to live an active lifestyle (Ms. Petty downhill skied following her TKA until 2019), Ms. Petty has never had an issue with her Device. *Id.*

16. Dr. Herbert Bertram, an American Board of Orthopaedic Surgery-certified physician with over 30 years of experience, began using the Device in 2007 (one year before the alleged defect was introduced to the Device). Decl. of Dr. Herbert Morton Bertram III, Ex. H, ¶¶ 1, 6. From 2007 to 2011, he implanted over 600 Devices with "very positive" results. *Id.*, ¶ 8. In that five-year span, he estimated that he "only had to revise approximately five to seven Optetrak Finned Tibial Trays, or approximately 1% of all implants, due to tibial loosening." *Id.*, ¶ 8. These results far outperform the industry average, which he estimates to be "between 2% and 10%" for any TKR implant. *Id.*, ¶ 10. Consistent with the

literature, Dr. Bertram believes that "the most common reason for the tibial loosening following TKR surgeries involves cementation technique, especially with high-viscosity cement (HVC)," and any "loosenings of the Optetrak Finned Tibial Trays [would have] no relation to the design of the tray" but instead result from "intraoperative factors, primarily cementation technique." *Id.*, ¶¶ 11–12.

17. From approximately 1995 to 2021, Dr. Robinson—another American Board of Orthopaedic Surgery-certified physician and a professor of orthopaedics at the University of Miami Medical School—implanted more than 3,000 Optetrak knees, including Finned, Trapezoidal, and Fit tibial trays. Ex. C, ¶ 11. He concluded that, "[b]ased on [his] own experience implanting Optetrak knees, [his] thorough knowledge of the literature regarding the Optetrak knee lineage, and [his] personal experience with the finned tibial design, there is no basis to believe that the [Device] has any design flaws or defects." *Id.*, ¶ 23.

18. There were no changes to the tray between 2003 and 2008 (the timeframe Relators allege a change occurred).[11] *See* Optetrak Cemented Finned Tibial Tray technical print/drawing (EXACTECH00722629), Ex. I; Ex. A, ¶ 9.

D. Tibial loosening is a well-known risk for TKAs.

19. Aseptic loosening is the most common reason for TKR revisions. Ex.

[11] The changes to the Device in 2008 were cosmetic and non-substantive, affecting only the logo and the shadow box size. Ex. A, ¶ 9. Neither implicates the Device's performance.

C, ¶ 12. All surgeons and manufacturers have experienced tibial loosening. *Id.*, ¶ 12; Ex. D, 109:19–110:1. Relators admit that there is a baseline revision rate for any TKA surgery regardless of the manufacturer. Ex. D, 104:8–105:15; Ex. R, 103:15–105:6 ("that's life, there's going to be some failures").

20. The primary causes of loosening are intraoperative factors, especially cementation technique and device alignment. Ex. C, ¶ 14; Ex. D, 97:1–101:20.

21. For CMS to deny coverage of the Device for Medicare beneficiaries, i.e., conclude the Device is not "reasonable and necessary," it would require CMS to approve a national coverage determination (NCD) or a Medicare Administrative Contractor (MAC) to approve a local coverage determination (LCD) finding specifically that the Device is not reasonable and necessary for primary TKAs. . *See* 42 U.S.C. §§ 1395h, 1395kk-1, 1395ff; 42 C.F.R. § 405.1062.

22. The Medicare statute does not define what is "reasonable and necessary." SSA 1862(a)(1)(A). Instead, it delegates the administration of benefits—including the determination of whether a particular item is covered—to the Secretary of the Department of Health and Human Services and authorizes the Secretary to carry out the administration of benefits through contracts with MACs, which use NCDs and LCDs to assist with their claims-processing responsibilities by establishing binding rules regarding whether specific items or services are covered on a nation-wide (NCDs) or a contractor-wide (LCDs) basis. *See* SSA §§

1816, 1874A, and 1869 (codified at 42 U.S.C. §§ 1395h, 1395kk-1, and 1395ff).

23. There is no NCD for TKR procedures. The applicable LCDs cover TKRs without regard to which manufacturer's device is used. *See*, *e.g.*, First Coast Service Options, Inc., L32078—Major Joint Replacement (Hip and Knee) (effective 10/16/2011 to 9/30/2015 in Florida, Puerto Rico, and the Virgin Islands); Cahaba Government Benefit Administrators, LLC, L32971—Surgery: Major Joint Replacement (Hip and Knee) (effective 4/1/2013 to 9/30/2015 in Alabama, Georgia, and Tennessee). The applicable LCDs simply require a device to be FDA approved or cleared and to comply with FDA regulations. *Id.* Safety and efficacy can be reviewed by CMS or MACs in the context of making individual claim determinations and establishing LCDs and NCDs, but it is extremely rare for CMS to conclude that a specific device is not covered for FDA-approved indications. *Id.*

24. Absent the applicability of a NCD or LCD to a particular item or service, a MAC determines whether the item or service is "reasonable and necessary" on a case-by-case basis and has flexibility to consider each patient's individualized medical needs as reflected in the patient's medical records. *See* 78 Fed. Reg. 48,164, 48,165 (Aug. 7, 2013).

25. To receive reimbursement payment, a hospital submits a claim electronically to the MAC for payment and processing. Decl. of Gregory Russo, Ex. GG, ¶ 18. The MAC determines whether the claim is appropriate for payment

and, if so, what the payment should be. *Id.* The MAC then sends payment information back to the provider, along with applicable payments. *Id.*

E. Any instances of tibial loosening of the Optetrak Finned Tibial Tray stemmed from intraoperative factors.

26. Exactech is committed to ensuring the safety and efficacy of its devices. Ex. A, ¶ 11. When it receives reports of revisions due to tibial loosening, Exactech investigates and studies all medical information it can obtain in an effort to determine the likely cause of the loosening. *Id.* Following appropriate investigations into each report of tibial loosening involving the Device, Exactech determined that the cause of the loosening was unrelated to the Device itself and instead caused by intraoperative factors. *Id.* Exactech concluded that no MDR or Adverse Event report was required. *Id.*, ¶¶ 11–12.[12]

27. When a manufacturer concludes that a device did not malfunction and that there was no device-related death or serious injury, it is not obligated to report that event. Decl. of Theodore M. Thompson II, Ex. FF, ¶¶ 5–8 (citing 21 C.F.R. §§ 803.50(a), 803.20(c)(2)). A manufacturer's decision to not report a complaint resulting solely from surgical technique is "objectively reasonable." *Id.*, ¶ 8. Moreover, there is no authoritative FDA guidance to the contrary that would

[12] Contrary to Relator Farley's belief, manufacturers are not obligated to report every instance of tibial loosening of which it is aware. *See* Ex. S, 228:1–21 (explaining that it's his understanding that trauma-induced revisions, such as a "car wreck" or "skiing accident," must be reported).

militate against Exactech's decision to not submit an Adverse Event report following its investigations into the rare instances of tibial loosening. *Id.*, ¶ 9.

28. Exactech has consistently found that intraoperative factors—as they relate to cementation and alignment of the Device, in particular—are the likely causes of aseptic loosening involving the Optetrak Finned Tibial Tray. Ex. C, ¶ 14; Ex. A, ¶ 12; Deposition of B. Thompson, Corporate Rep., Ex. J, 222:22–223:13.

29. Dr. Petty is aware of just three physicians who had aseptic-loosening issues, Drs. McCloud, Moody, and Lemak, and he concluded that those loosening issues related to their cement technique. Ex. B, 212:6–216:5. Dr. Petty reached this conclusion by attending and observing surgery with Dr. McCloud, watching a video of Dr. Moody's surgery, and analyzing x-rays of Dr. Lemak's surgeries. *Id.*, 215:9–216:5. Specifically, Dr. Petty attended surgery with Dr. McCloud to observe his cement technique. He provided advice and coaching to Dr. McCloud with regard to his cement and alignment technique, and subsequently, Dr. McCloud's instances of loosening dramatically decreased. *Id.*, 215:20–23; 466:21–467:23. Dr. Petty reviewed a video of Dr. Moody's surgery. He determined that Dr. Moody's loosening issues stemmed from his cement technique. Once Dr. Moody corrected his technique, Dr. Moody had "great results with his patients." *Id.*, 214:1–12; 216:1–2; 455:10–13. In fact, Dr. Moody noted in 2003 that the 10 loosenings he experienced out of about 350 procedures using the Optetrak device "resulted as a

consequence of motion prior to cement polymerization" and "the common thread is Cemex," a brand of cement. Ex. A, ¶ 13 (Ex. C).

30. Dr. Petty offered many times to attend Dr. Lemak's surgeries, but Dr. Lemak always refused. Ex. B, 316:1–4. Even so, Dr. Petty analyzed some x-rays and noticed Dr. Lemak's poor cement technique. Ex. B, 315:1–316:4; 215:6–19.

31. Dr. Ivan Gradisar, whose surgical group has implanted thousands of Optetrak Finned Tibial Trays, examined tibial loosening within his own group. Ex. C, ¶ 28. He found that the rare instances of loosening involving Optetrak Finned Tibial Trays were a result of poor cementing technique, including (a) flexing the implant before the cement cures; (b) failing to seat the implant using constant pressure; (c) failing to keep the cement interfaces clean and dry; and (d) failing to prevent fat "blowback," which can cover the cement and compromise the bond. *Id.*, ¶ 28; ECF No. 54-1 (Gradisar audit attached to Am. Compl.), Ex. K.

32. Exactech asked Dr. Gradisar to perform an audit of his experience implanting the Optetrak Finned Tibial Tray because he maintained a personal registry dating back to 1994, and because he is a world-renowned surgeon, respected by even the Relators. Ex. A, ¶ 14; Ex. D, 97:1–101:20, 150:9–10 (Relator Fuentes explaining that "I respect Dr. Gradisar highly"), 309:3–4 (Drs. Robinson and Gradisar are "really good surgeons").

33. Dr. Young-Hoo Kim and his colleagues reported similar results. *See*

Ex. L. In that 11-year study using the finned fixed bearing modular tray and posterior stabilized design, none of the study's 131 patients who received Optetrak knees experienced aseptic loosening. *Id.* The authors concluded that the Optetrak knee—with its 99% survival rate—"obtained favorable clinical and radiographic results." *Id.*; *see also*, Ex. C, ¶ 25.

34. Other surgeons have had similar, successful results with the Optetrak knee system. In 2004, Dr. John Edwards and other surgeons prepared a paper documenting one surgeon's 8.5-year experience with the Optetrak system (using a near-even split of Finned and Trapezoid trays). *See* Ex. M. That surgeon performed 1,526 TKR surgeries, had a reoperation rate of just 1.4% for any reason (not just aseptic loosening), and had no reoperations to replace the Device due to tibial-femoral instability. *Id.*; *see also*, Ex. C, ¶ 24.

35. Despite these surgeons' positive results with the Device, it is not in dispute that cementing and alignment technique can affect every TKA surgery regardless of the manufacturer. Ex. C, ¶¶ 12–19. For example, in 2013 a team of physicians published a paper addressing the importance of medium-viscosity cement to promote cement penetration and the necessity for longer cement-cure time. *See* Ex. N. A similar study published in 2019 found that revision rates for surgeons using high-viscosity cement was "significantly higher" compared to surgeons using low-viscosity cement. *See* Ex. O. Finally, in addition to cementing

technique, the misalignment of the knee prosthesis can result in increased instances of tibial loosening. *See* Ex. P; *see also* Ex. C, ¶¶ 12–19.

36. Exactech became aware of isolated "clusters" of loosening cases in Australia and France. In 2008, Exactech learned of a surgeon-specific "cluster" in Australia after data from the Australian national registry indicated a higher-than-expected revision rate. Ex. A, ¶ 15. Exactech investigated and requested the registry's data, which showed that 50 of the 60 revised knees were implanted at the same hospital by just three different surgeons. *Id.* Exactech further determined that the prostheses were often not properly aligned during the procedures because the surgeons were not using the correct equipment, among other things. *Id.*

37. Similarly, in 2012, Exactech learned that Lille University Hospital in France experienced tibial loosening in 9 of 110 knees (more than one-half of which were implanted by the same surgeon). *Id.*, ¶ 16. Thelu *et al.* published an article regarding the hospital's loosening experiences. *Id.* Exactech representatives met with the surgeons and examined patient x-rays. *Id.* After a thorough investigation, it was apparent that the Thelu conclusions were based on incorrect information and a flawed understanding of the true causes. *Id.*; *see also* Exactech's published response, Petty *et al.*, *Commentary on an Article by C.E. Thelu et al.: "Poor Results of the Optetrak Cemented Posterior Stabilized Knee Prosthesis After a Mean 25-month Follow-up: Analysis of 110 Prostheses,"* 98 ORTHOPAEDICS &

TRAUMATOLOGY: SURGERY & RESEARCH 706 (2012)), Ex. Q. First, the surgeons were using other manufacturers' instruments to align a majority of the knees. Ex. Q. In its published Instructions for Use (part of the FDA's clearance), Exactech expressly warns against using other manufacturers' instruments because Exactech cannot ensure that its components are compatible with those instruments. *Id.* Second, the surgeons used improper alignment technique. *Id.* Third, during cement polymerization, the surgeons loaded the knee in maximum extension, without the slight bend in the knee joint that Exactech recommends. *Id.* Failing to follow manufacturer instructions explains those surgeons' poor results. *Id.*

F. Exactech carefully scrutinizes every consulting agreement to ensure they conform with federal laws and regulations.

38. Prior to entering a consultancy arrangement with a physician, Exactech performs a thorough, needs-based analysis to ensure each agreement has a valid purpose and that Exactech provides fair-market value to the physician for his or her services. Ex. A, ¶ 18; Ex. J, 191:9–13; Ex. D, 217:10–18.

39. Moreover, in 2010, Exactech entered into a Deferred Prosecution Agreement (DPA) and a Corporate Integrity Agreement (CIA) with the Department of Health and Humans Services Office of Inspector General. Ex. J, 24:22–25:2, 185:6–17. Those agreements required Exactech to bolster its already strong compliance policies and procedures related to consulting arrangements, further eliminating any potential for consulting agreements to be used for any

improper purpose. *Id.*, 209:11–211:8. As part of those agreements, an independent-review organization reviewed each consulting agreement for a period of five years, beginning in December 2010. Ex. A, ¶ 18.

40. In 2016, Exactech considered entering into a consulting arrangement with Dr. David G. Lemak. Ex. J, 172:17–171:10. Exactech engaged Dr. Lemak to assist with its biologics line of business.[13] *Id.*, 177:9–21; Deposition of Brooks Wallace, Ex. R, 213:16–219:16. Early in the consulting relationship, Exactech learned that because Dr. Lemak's hospital already carried a similar biologics product at its hospital on an exclusive basis, Dr. Lemak could not perform the product evaluation work contemplated by the consulting arrangement. Ex. J, 175:13–176:22; Ex. R, 213:16–219:16. In the absence of a legitimate need for a consulting relationship, Exactech was unable to move forward with the arrangement. Ex. J, 175:13–176:22; Ex. A, ¶ 18. Dr. Lemak was paid fair-market compensation for the preliminary work he performed, including attending meetings and the time he billed to prepare for the meetings. Ex. J, 174:8–175:8; Ex. A, ¶ 18.

G. Relators filed their *qui tam* action, and the federal government and each state declined to intervene.

41. Relators filed their initial complaint on June 29, 2018, alleging claims on behalf of the federal government and 26 Plaintiff States. ECF No. 1.

[13] Exactech's biologic products include collagen, bone void filler, plasma, bone grafts, and bone marrow concentrate. Exactech Dec., Ex. A, ¶ 18.

42. After a thorough investigation, on August 7, 2019, the United States Department of Justice (DOJ) and the Plaintiff States filed their Notice of Election to Decline Intervention. ECF No. 18.

43. On August 8, 2019, the complaint was unsealed. ECF No. 19. Exactech moved to dismiss it in its entirety on December 20, 2019. ECF No. 37.

44. Judge Axon dismissed the complaint on February 14, 2020, as an "impermissible shotgun pleading." ECF No. 49.

45. On March 2, 2020, Relators filed their Amended Complaint, the operative complaint in this case. ECF No. 54 (Am. Compl.).

H. Relators' "Perfect Storm" Theory.

46. Relators testified that the higher-than-expected failure rate—alleged to be approximately 30–35%—was a result of a "perfect storm" of issues. Am. Compl., ¶ 114; Ex. D, 70:13–71:15; Ex. R, 313:13–23. According to Relators, the Optetrak Finned Tibial Tray "was performing well" from 1994 until 2008, but "after 2008 the company started seeing increasing reports of tibial loosening." Ex. D, 70:13–71:3. They asserted that "two factors were the main drivers for the Optetrak finned tibial tray['s]" change in performance: the "introduction of the low profile instrumentation that didn't have a fudge factor," and "the change or perceived change to the coating." *Id.*, 168:10–169:9.

I. The evidence in this case is logically incompatible with Relators' design-defect theory.

47. Relators did not rely on actual, statistically valid performance data for the Device to establish an estimated failure rate. Instead, they guessed. Relator Fuentes admitted at his deposition that he extrapolated the alleged failure rate of 30–35% based on conversations he had with just three physicians in Guatemala, Argentina, and Italy (none of whom practice in the U.S.). Ex. D, 134:19; 136:23; 137:4; 130:4–6; *see generally id.*, 121:3–137:10.

48. When Relator Farley was asked to explain the basis for the alleged failure rate, he said, "I can't calculate it because I don't know. . . . I mean, to me it's the studies [that] show what the failure rates are." Deposition of Robert Farley, Ex. S, 194:6–7; 195:17–18. When asked to identify the total number of times the Optetrak Finned Tibial Tray failed, Relator Farley testified, "I don't believe Exactech would give us that information." *Id.*, 194:20–21. Finally, when asked point blank whether he had an independently calculated failure rate, Relator Farley replied that he did not: "Just what [Relator] Manny [Fuentes] tells me." *Id.*, 196:8.

49. Relator Wallace also has no personal knowledge of how Relators calculated the "overall" failure rate: "I believe that probably would have come from Manny." Ex. R, 315:17–18. And, Relator Wallace stated, "I don't know if we did [the calculation of Dr. Lemak's failure rate] originally first. I don't know if our attorneys did it and put it into the complaint." *Id.*, 222:13–16.

50. Dr. Hutchins estimated that he had "somewhere between 15 to 30" revision surgeries related to tibial loosening out of approximately "350 to 400" total procedures using the Device, for a rate of approximately 3.75% and 7.5%. Deposition of Dr. Christopher Hutchins, Ex. T, 35:18–23; 38:10–15.

51. Dr. Wayne Moody testified that he had a revision rate of around "seven percent" in a four-and-a-half year timeframe using the Device from 2001 to 2005. Deposition of Dr. Wayne Moody, Ex. U, 132:20–133:3; 135:11–12.

52. Dr. Hutchins testified that he last used the Device in approximately 2006 or 2007, Ex. T, 35:5–17, and Dr. Moody last used the Device in 2006. Ex. U, 194:16–195:4. Both Drs. Hutchins and Moody last *reported* issues with loosenings in 2006—for surgeries that occurred at least two to three years earlier. Ex. T, 45:14–46–15; Ex. U, 166:13–167:2.

53. All cases of early tibial loosening Drs. Moody and Hutchins reported occurred in primary surgeries from well before 2008, when Relators alleged the surreptitious changes occurred. *See* Ex. T, 45:14–46–15; Ex. U, 166:13–167:2.

54. Exactech asked for all documents that support Counts I, II, and V. Relators responded the same way for all requests: "[R]elators are producing all relevant documents in their possession responsive to this request. See documents bated RELATORS000001–[]709." Relators' Supp. Resp. to Exactech's Document Requests (Set One), Ex. Z at 11–16.

J. Dr. Lemak.

55. Dr. Lemak's alleged surgical issues are front and center in Relators' case; his name appears in the Amended Complaint 144 times, far more than any other surgeon. *See* Am. Compl. Relators point to six patients of Dr. Lemak who allegedly received a "defective" Device that "failed prematurely" causing a revision surgery. *Id.*, ¶ 146. Relators also allege that these patients were Medicare-insured patients. *Id.*, ¶ 146. Relators point to five redundant spreadsheets they produced, which state that Patients A–P received a revision surgery at some point. *See* Exs. AA, BB, CC, DD, and EE. These spreadsheets do not establish that the federal government paid for any of these Devices. And hidden in column AE of these spreadsheets is device information noting that several patients received devices that are not the Finned Tibial Tray (and for those who received finned trays, they had the Logic Finned Tibial Tray that came on the market around 2009, not the Optetrak Finned Tibial Tray). *See* Exs. AA, BB, CC, DD, and EE.

56. Relators did not seek written discovery from Dr. Lemak, but they did take his unilateral deposition without noticing Exactech or allowing Exactech to participate. ECF No. 137 (Mot. in Limine, or in the Alternative, Mot. for Protective Order, to Exclude Testimony of Dr. David G. Lemak). They have withheld Dr. Lemak's transcribed statement on the basis of the work-product doctrine. *See id.*

57. On the other hand, Exactech issued written discovery to Dr. Lemak to

test the sufficiency of Relators' allegations. *See* ECF No. 137-2 (Dr. Lemak's responses to Exactech's document requests). Exactech also sought to depose Dr. Lemak, but Dr. Lemak refused to permit his attorney to accept service. *See* ECF No. 137-4 (email from B. Robertson explaining that "my client . . . does not authorize us to accept service" of the deposition subpoena). Despite six attempts to serve him at his houses and place of business, Exactech was unable to obtain his testimony through deposition. *See* ECF No. 137-5 (Affidavit of Jeff Abbett).

58. Dr. Mark Davis analyzed the patient records, x-rays, and radiological images of 60 patients of Dr. David G. Lemak who received TKR surgeries. Decl. of Dr. Mark B. Davis, Ex. W, ¶¶ 9–10. In analyzing Dr. Lemak's x-rays for the primary surgeries that required revisions, he identified four categories of surgical-technique errors in Dr. Lemak's surgeries. *Id.*, ¶ 11. First, he observed several instances of joint imbalance. *Id.* Second, Dr. Davis determined that Dr. Lemak often failed to properly align the components with the tibia and femur bone. *Id.* Third, Dr. Lemak did not use the proper amount of cement, often using an insufficient amount and failing to reinforce the implant by placing enough cement in the tibial canal.[14] *Id.* And fourth, Dr. Lemak used improper cementation techniques such as failing to allow the cement to harden before moving the joint.

[14] This is consistent with Luis Alvarez's testimony that Relator Wallace approached him concerned that Dr. Lemak was using insufficient amounts of cement. Ex. X, 185:7–186:13.

Id. All of these issues, or a combination of each of these issues, were present in the x-rays Dr. Davis analyzed from Dr. Lemak's primary surgeries, and his revision surgeries. *Id.* Dr. Davis concluded that the surgical-technique errors identified above would contribute to an increase of instances of aseptic tibial loosening. *Id.*

59. During a surgery attended by an Exactech employee, Dr. Lemak became "very agitated when he was trying to implant the knee," eventually gave up, leaving the surgery prior to completing the operation. Ex. Y, 330:16–331:14.

K. Defendants failed to establish that any consulting agreement was entered into for an improper purpose.

60. Exactech asked Relators to describe in "detail the factual knowledge [they] have to support" their allegation that any physician received an illegal consulting agreement. Relators' Supp. Responses to Exactech's Interrogatories (Set One), No. 6, Ex. V at 6–9. Relators responded by identifying ten physicians—including Dr. Lemak—who allegedly received illegal consulting agreements. *Id.* For all ten physicians, Relators provided the identical answer: "Relator Dr. Fuentes has knowledge based on his role as an Exactech surgeon liaison." *Id.* Relators have not supplemented their interrogatory responses since Relator Fuentes provided his testimony on October 29, 2021. During his deposition, however, Dr. Fuentes admitted that he did not have any admissible evidence of any illegal consulting agreements. Ex. D, 247:18–248:6. Instead, Relator Fuentes described his knowledge as a "general sense" that Exactech entered these ten agreements for the

purpose of keeping the physicians' business. *Id.* When asked to explain his knowledge of Dr. Lemak's agreement, Relator Fuentes testified, "I don't know him." *Id.*, 244:10. He then admitted that his interrogatory answer was "incorrect." *Id.*, 245:5. Similarly, with respect to Dr. Slater, Relator Fuentes admitted, "I don't really remember what [the] exact detail was regarding Dr. Slater. I cannot picture him. I don't remember." *Id.*, 242:17–243:4.

61. Also in response to Interrogatory No. 6, Relator Fuentes stated that "as an Exactech surgeon liaison, [he] had access to documents, records, and other Exactech employees that identify the individuals with whom Exactech had consulting agreements." Ex. V at 6–9. Yet Relator Fuentes testified that "[he] never had access to … the real document and/or the needs assessment [for each consulting agreement] because that wasn't" his area of responsibility. Ex. D, 237:17–20. Instead of "documents, records, and other Exactech employees" as alleged in the Amended Complaint, Relator Fuentes testified that the allegations were based on his hunch that the agreements were for improper purposes. *Id.*, 247:18–23 (admitting it was a "general sense" that the agreements were unlawful).

62. Relator Wallace, despite not providing any answer to Exactech's Interrogatory No. 6, *see* Ex. V at 6–9, believed that Dr. Lemak was a "[g]reat candidate" for the sports-medicine design team for which Exactech paid him a consulting fee. Ex. R, 215:20–216:2. Relator Wallace then admitted that Dr.

Lemak performed the work he was paid to do (e.g., starting to develop a "shoulder sports medicine line" and attending "several meetings" with Exactech). Ex. R, 216:3–219:16. Relator Wallace's only issue was that the arrangement did not move forward after the initial phase. *Id.*, 219:11–16.

STANDARD OF REVIEW

Summary judgment is appropriate when the Court is satisfied that the materials in the record demonstrate that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–24 (1986); Fed. R. Civ. P. 56(a).

LEGAL STANDARDS GOVERNING FALSE CLAIMS ACT CASES

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).[15] The submission of a false or fraudulent claim for payment is "[t]he *sine qua non* of a[n] [FCA] violation." *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *see also U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170, 1173 (9th Cir. 2006) ("[F]or a false statement or course of action to be actionable . . . , it is necessary that it

[15] Relators' allegations span from April 2008 to December 2016. Am. Compl. ¶¶ 98, 157, 204(b). On May 20, 2009, Congress enacted the Fraud Enforcement Recovery/Remedies Act ("FERA"), amending 31 U.S.C. § 3729(a). Except where specifically noted, the amendments to § 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(G) are not material because Relators fail to show any falsity or knowledge, essential elements under both versions of the FCA.

involve an actual [false] *claim* . . . ."). This is because the FCA attaches liability, "not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" *Clausen*, 290 F.3d at 1311.

Relator must do more than show a regulatory violation: "Liability under the [FCA] arises from submission of a fraudulent claim to the government, not the disregard of government regulations." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005); *Marsteller v. Tilton*, 880 F.3d 1302, 1312 (11th Cir. 2018) (FCA "is not an all-purpose antifraud statute [] punishing garden-variety breaches of contract or regulatory violations" (quotations and alterations omitted) (quoting *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016))).

Showing improper practices is insufficient to prove an FCA violation absent showing "that a specific fraudulent claim was in fact submitted to the government." *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009). The "fact that there may have been a violation of the [Medicare] laws . . . is not enough." *U.S. ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017); *see Clausen*, 290 F.3d at 1311 (the FCA "does not create liability merely for a health care provider's disregard of Government regulations.").

A person violates the FCA only if he knowingly causes a false claim to be presented to the government for payment. 31 U.S.C. § 3729(a)(1)(A). A relator "must show that the defendant acted 'knowingly,' … define[d] as either 'actual

knowledge,' 'deliberate ignorance,' or 'reckless disregard.'" *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015) (quoting 31 U.S.C. § 3729(b)). "[L]iability does not attach to innocent mistakes or simple negligence." *Id.* The "falsity" must be "knowingly perpetrated." *U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902 (9th Cir. 2017); *see Hindo v. Univ. of Health Scis.*, 65 F.3d 608, 613 (7th Cir. 1995) ("In short, the claim must be a lie.").

ARGUMENT

I. The only credible evidence in this case establishes that the Device is a safe and reliable TKA implant. Relators' FCA claims (Counts I & II) fail because Relators have no substantial evidence that Exactech knowingly submitted, or caused to be submitted, a false claim for reimbursement to a federal healthcare program.

Relators' first two Counts allege a violation of 31 U.S.C. § 3729(a)(1)(A). *See* Am. Compl. ¶¶ 204–11. Relators "must prove three elements": (1) that Exactech presented, or caused to be presented, a claim for payment; (2) that the claim was false; and (3) that Exactech knew the claim was false. *Phalp*, 857 F.3d at 1154 (citing § 3729(a)(1)(A)). Relators cannot prove any of these elements.

A. *Presentment-of-a-Claim:* Relators have no evidence that any "claim" to CMS was for a Device that actually failed.

The submission of a false claim for payment is "[t]he *sine qua non* of a[n] [FCA] violation." *Clausen*, 290 F.3d 1311. Relators must present evidence at this stage that a claim was presented to CMS *for a Device that actually failed as a*

result of a design defect. *See Carlisle v. Daewon Kangup Co.*, No. 3:15CV565-CDL, 2018 WL 3199148, at *3–4 (M.D. Ala. Mar. 29, 2018). They have none.

Relators point to six specific patients of Dr. Lemak who allegedly received "defective" Devices that "failed prematurely" and were revised. Am. Compl. ¶ 146; *see also* ECF No. 63 (Mem. of Opinion on Exactech's Mot. to Dismiss) at 37.[16] Relators also allege that these patients were "Medicare and Medicaid insured patients." Am. Compl. ¶ 146. Relators, however, did not develop or produce any evidence to support these allegations. Relators' only evidence are five redundant spreadsheets they produced, concluding that Patients A–P received a revision surgery at some point. *See* SF ¶ 57. But these spreadsheets do not establish that the government paid for any of these devices, and hidden in column AE of these spreadsheets is information noting that several patients received devices that are not the Finned Tibial Tray (and for those who received finned trays, they had the post-2009 Logic Finned Tibial Tray and not the Optetrak Finned Tibial Tray). *See* SF ¶ 57. Relators have not produced any evidence tying any of Dr. Lemak's six patients—or any other patient for whom premature tibial loosening necessitated a revision surgery of the Device—to a single claim submitted to CMS for payment.

Relators admit (as they must) that there is a baseline revision rate for any TKA regardless of the manufacturer. SF ¶ 21. As such, some meaningful number

[16] Exactech refers to this Memorandum of Opinion as "Order" in the Brief.

of revisions necessarily occur, no matter the design and pedigree of the product. SF ¶ 21. Given this reality, Relators must provide evidence of specific revisions that occurred because the Device was defective. Stated differently, Relators must differentiate the actionable claims—those submitted to the government for reimbursement based on procedures involving a defective Device—from claims that are not actionable—for myriad reasons, including that the Device did not prematurely loosen, the revision surgeries were performed for reasons unrelated to the Device, a private insurer reimbursed the claims, or other reasons. *See Carlisle*, 2018 WL 3199148, at *3–4 (holding that the relators must identify "specific vehicle[s]" that contained the "allegedly defective parts manufactured by the defendants"). Relators cannot bypass their obligations of proof by relying on unfounded assertions that all post-2008 Devices are defective. SF ¶ 48.

This evidentiary deficiency highlights a critical shortcoming in Relators' case. Relators' FCA claims are not FCA claims at all—they are products-liability claims masquerading as FCA claims. That is an improper use of the statute. *See U.S. ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822–23 (8th Cir. 2009) (finding that "allegations of consumer injury and non-compliance with the [FDA's Medical Device Reporting Regulations]" were insufficient to show an FCA violation); *U.S. ex rel. Provuncher v. Angioscore, Inc.*, No. CIV.A. 09-12176-RGS, 2012 WL 3144885, at *1–2 (D. Mass. Aug. 3, 2012) (dismissing FCA claims

alleging that AngioScore deliberately suppressed Adverse Event reporting of injuries and incidents involving angioplasty catheters because "the provision of a sophisticated medical device that almost inevitably will be subject to a statistically predictable failure rate, is not the evil that Congress sought to root out by passage of the [FCA]," and noting that, if patients are harmed by the device, "their recourse is to state and federal products liability laws and not to the [FCA]").

Ultimately, Relators have no competent proof that any claims were submitted to CMS for a Device that actually failed because of a design defect.

B. *Falsity:* Even if Relators could show that a claim was submitted to the government, Relators cannot prove that any claim was false or fraudulent because the Optetrak Finned Tibial Tray was and is a safe and reliable TKA Device.

A claim may be false under the FCA if it is either factually or legally false. *See U.S. v. Space Coast Med. Assocs., L.L.P.*, 94 F. Supp. 3d 1250, 1259 (M.D. Fla. 2015). Relators try to establish legal falsity through a false-certification theory, namely that the Device was both "misbranded" under FDA regulations, and not "reasonable and necessary" and thus not reimbursable by Medicare. Am. Compl. ¶¶ 1, 101, 204. There is no competent evidence to support either theory.

Under either theory, Relators must show that the Device was so defective that it was "worthless" and should not have stayed on the market. *See Roop*, 559 F.3d at 824. Yet according to Relators' own deposition testimony, the Device "was performing well" from 1994 until 2008. SF ¶ 48. At that point, Relators assert a

"perfect storm" rendered it defective, resulting in increasing reports of tibial loosening. *Id.* Relators attribute this to two key factors in 2008: (1) the introduction of low-profile instrumentation that no longer included a "fudge factor," and (2) an alleged change to the surface coating of the Device. *Id.*

Relators' allegations are baseless. The design-history files and related blueprint drawings do not show any design changes around the 2008 timeframe. SF ¶ 20. Moreover, Relators' "perfect storm" is chronologically impossible. Relators allege that the "perfect storm" occurred in 2008. SF ¶ 48. To support their theory that the "perfect storm" resulted in higher-than-expected revision rates, they point to Drs. Hutchins's and Moody's revisions, which occurred at the latest in 2006, for primary surgeries performed years earlier, in 2003 or 2004. SF ¶ 55. For those primary surgeries prior to 2006, Drs. Hutchins and Moody could not have used the low-profile instrumentation or allegedly redesigned tray from 2008.[17]

This leaves Dr. Lemak as the only physician referenced in the Amended Complaint for whom any evidence was developed during discovery. But even that evidence does not align with Relators' theory: for example, there is no evidence that Dr. Lemak used the low-profile instrumentation that is part of Relators' alleged "perfect storm." Rather, the facts show that Dr. Lemak used poor surgical

[17] Nor, of course, would any claims for reimbursement for those surgeries be actionable under the FCA because they would have been presented for payment more than ten years before Relators filed this action on June 29, 2018. *See* 31 U.S.C. § 3731(b).

technique and was very temperamental. *See* SF ¶ 60 (identifying four categories of surgical-technique errors by Dr. Lemak); SF ¶ 61 (during one surgery, Dr. Lemak became "very agitated when he was trying to implant the knee," eventually gave up, and left the operating room prior to completing the surgery); ECF No. 1, Initial Complaint, ¶ 186 ("Dr. Lemak was consistently cursing at Relator Wallace" during one surgery); SF ¶ 60 (Relator Wallace was concerned that Dr. Lemak was using insufficient amounts of cement).

The regulatory nature of their allegations and the timing mismatch are both fatal to Relators' case. In addition, the population size is statistically insignificant and inconsistent with a device-defect theory. Over 500 physicians in the U.S. have used this Device, yet Relators rely on just three physicians who had issues, only one of whom performed surgeries using the Device after the alleged defect arose. No reasonable juror that could find that a heavily regulated medical Device is defective where only a single user out of 514 surgeons reported any significant post-2008 issues involving the performance of the Device.[18]

Leaving aside these fatal factual and logical flaws in Relators' theory, Relators also provide inadequate legal support for their allegations. As this Court

[18] Exactech is aware of a handful of other surgeons who experienced tibial loosening, including 8 surgeons who reported loosenings during clinician feedback meetings in 2006 and 2008 (half reporting only one or two over several years), Dr. Gradisar and his colleague (as reflected in his audit), and the clusters of surgeons in France and Australia. *See* ¶¶ 33–34, 38–39. But Relators have no testimony from those surgeons and no evidence that the cause of those loosenings is anything other than intraoperative factors, as the audit and the Thelu response explain.

pointed out, a device is "reasonable and necessary" if it is "'safe' and 'effective' ... that is, ... [if it] has been proven safe and effective based on authoritative evidence, or alternatively, ... is generally accepted in the medical community as safe and effective for the condition for which it is used." Order at 32 (quoting 54 Fed. Reg. 4302–04). The evidence shows that the Device satisfied this standard. SF ¶¶ 18, 19, 33, 36. Anecdotal evidence of a small handful of surgeons does not compare to the wealth of statistical data generated over years of use by over 500 U.S.-based surgeons. Indeed, Relators' baseless attack on the Dr. Ivan Gradisar's character (*see* Am. Compl. ¶¶ 72–79) can been seen as recognition that his report, based on meticulous contemporaneous record-keeping, shows that revisions related to loosening were a function of interoperative factors and not a flaw in the Device. SF ¶ 33.

Conclusory allegations that the government "'would not have reimbursed through Medicare individuals submitting claims [for Optetrak systems] if [they] had known of the defects and failure to comply with the rules and regulations of the FDA' do[] not comply with Rule 9(b)," *Roop*, 559 F.3d at 825, let alone meet the evidentiary requirements for summary judgment. CMS has never taken the step to deem the Device not "reasonable and necessary" such that it would deny coverage for a procedure involving the Device. SF ¶¶ 23–26. To do so would require CMS to approve a national coverage determination (NCD) or a MAC to

approve a local coverage determination (LCD) establishing that the Device is not reasonable and necessary for primary TKAs. No such NCD, LCD, or CMS guidance exists.[19]

There is no NCD for TKRs. SF ¶ 25. The applicable LCDs cover TKRs without regard to which manufacturer's device is used. *See id.* They simply require the devices to be FDA approved and to comply with FDA regulations. What's more, the LCD appliable in Alabama from 2013 to 2015 states that a revision TKA can be "necessary" and covered by Medicare when "loosening … of one or more components" occurs after the primary TKA. Cahaba Government Benefit Administrators, LLC, L32971—Surgery: Major Joint Replacement (Hip and Knee). MACs and CMS are aware that loosening may occur and understand that it is reasonable and necessary to cover the revisions (consistent with the knowledge that TKA devices are subject to a statistically predictable failure rate).

Lastly, Relators conflate the statutory mandates of CMS and FDA, each of which review product safety and efficacy, but for different purposes. *See* 78 Fed.

[19] The Medicare statute does not define what is "reasonable and necessary." Instead, this role is delegated to CMS Medicare Administrative Contractors (MACs). SSA §§ 1816, 1874A, 1869 (codified at 42 U.S.C. §§ 1395h, 1395kk-1, and 1395ff). MACs use NCDs and LCDs to assist with their claims-processing responsibilities by establishing binding rules for whether specific items or services are covered on a nation-wide (NCDs) or a contractor-wide (LCDs) basis. MACs may use LCDs that are binding on providers in their service areas as long as those LCDs do not contradict NCDs. 42 C.F.R. § 405.1062. Absent an applicable NCD or LCD, MACs decide whether items or services are "reasonable and necessary" on a case-by-case basis, based on each patient's individualized medical needs. 78 Fed. Reg. 48,164, 48,165 (Aug. 7, 2013).

Reg. 48,164, 48,165 (Aug. 7, 2013) (CMS provides "generally applicable rules to ensure that similar claims for items or services are covered in the same manner"). Safety and efficacy can be reviewed by CMS or its contractors in the context of making individual claim determinations and establishing LCDs and NCDs, but they rarely conclude that a device is not covered for FDA-approved indications.

Relators do not allege, nor have they shown, that the Device has ever been the subject of any negative coverage treatment. They cannot point to a single instance where the agency charged to adjudicate Medicare claims has determined that use of an Optetrak tibial component rendered a TKA claim not reimbursable. Accordingly, the Optetrak system is "reasonable and necessary" when implanted as part of an eligible TKR procedure, and Relators have no evidence to the contrary.

In an FCA case, "sales of a defective product do not give rise to FCA liability absent proof that a party 'knowingly or with deliberate ignorance charged the government for worthless services.'" *Roop*, 559 F.3d at 824. And "[i]n a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all." *Id.* That high standard cannot be met here, where only a few physicians reported elevated loosening rates, and many surgeons had enormous success with the Device.

C. *Knowledge:* Relators have adduced no evidence that Exactech knowingly sold a defective TKA implant.

The FCA's knowledge requirement is a "rigorous" one, *Escobar,* 579 U.S. at

192, designed to ensure that "liability does not attach to innocent mistakes or simple negligence," *Urquilla-Diaz*, 780 F.3d at 1058. The FCA penalizes "only those statements made with knowledge of their falsity." *U.S. ex rel. Yannacopolous v. Gen. Dynamics*, 652 F.3d 818, 832 (7th Cir. 2011); *see Urquilla-Diaz*, 780 F.3d at 1058. Under the false-certification theory, Relators must show that Exactech knew or should have known that its conduct violated regulations or statutes, *see Phalp*, 857 F.3d at 1154–55, and that such violation was material to the government's decision to pay for the Device. *See Marsteller*, 880 F.3d at 1312.

Relators allege that Exactech had knowledge of the false claims based on (1) the Device's allegedly high failure rate, (2) Exactech's alleged efforts to undertake a silent recall of the Device, and (3) its failure to report instances of loosening to the FDA. Relators have no evidence to support those speculative theories.

1. Exactech determined that intraoperative factors—not a design defect—were the cause of aseptic tibial loosening.

The Court held that Relators sufficiently alleged knowledge because, by "[n]o later than 2008, Exactech learned that the [Device] failed in approximately 30–35% of patients within the first three years of implantation." Order at 3, 45–46. At this stage, Relators must have evidentiary support for those allegations. They do not. There is no substantial evidence that Exactech knew, or should have known, that the Device was defective. Relators' allegations concerning the Device's failure rate were highly exaggerated guesses based on extrapolation from conversations

with mostly non-U.S. surgeons. Relators' speculative defect theory is logically flawed in terms of timing, relies on a statistically insignificant population size, and misconstrues governing legal standards. Uncontroverted evidence proves the Device's overall failure rate was well below industry average. SF ¶¶ 13, 16, 18.

Simply showing that Exactech was aware that a surgeon experienced higher-than-expected rates of premature tibial loosening after 2008 is not enough to establish a design defect, let alone falsity. When presented with questions about premature tibial loosening, Exactech consistently found that the Device functioned properly, and that intraoperative factors were the cause. These conclusions were bolstered by scientific literature and widespread positive results, including those detailed in formal patient registries. SF ¶¶ 33–37. The credible evidence demonstrates that physician technique is the key variable in outcomes, rather than the Device. Put another way, TKR devices have similar design characteristics: the surgeon and his/her technique are the keys to a successful surgery. SF ¶ 21. The following physicians have used and studied the Device, all with positive results.

- ***Dr. Petty***: Dr. Petty often personally investigated the rare reports of tibial loosening that Exactech received from physicians. SF ¶ 31. He testified that he only knew of three physicians who experienced higher-than-expected revision rates: Drs. McCloud, Moody, and Lemak. *Id.* He further testified that each of these physicians' issues were related to surgical technique, primarily cement technique. *Id.*

    - Dr. Petty attended surgery with Dr. McCloud. He provided advice and coaching to Dr. McCloud with regard to his cement and alignment technique, and subsequently Dr. McCloud's

instances of loosening dramatically decreased. SF ¶ 31.

- Dr. Petty reviewed a video of Dr. Moody's surgery. He determined that Dr. Moody's loosening issues stemmed from his cement technique. Once Dr. Moody corrected his technique, he had "great results with his patients." SF ¶ 31.

- Dr. Petty offered many times to attend surgery with Dr. Lemak, but Dr. Lemak always refused. In regard to litigation unrelated to this case involving Dr. Lemak, Dr. Petty analyzed some of Dr. Lemak's x-rays and determined that Dr. Lemak used poor cement technique. SF ¶ 32.

- ***Dr. Bertram***: Dr. Bertram, an American Board of Orthopaedic Surgery-certified physician with over 30 years of experience, began using the Device in 2007 (before the supposed "perfect storm" occurred). SF ¶ 18. From 2007 to 2011, he implanted over 600 Optetrak Finned Tibial Trays with "very positive" results. SF ¶ 18. In that five-year span, he estimated that he "only had to revise approximately five to seven Optetrak Finned Tibial Trays, or approximately 1% of all implants, due to tibial loosening." *Id.* These results far outperform the industry average, which he estimates to be "between 2% and 10%" for any TKR implant. Dr. Bertram further explained that "the most common reason for the tibial loosening following TKR surgeries involves cementation technique, especially with high-viscosity cement (HVC)," and that any "loosenings of the Optetrak Finned Tibial Trays [would have] no relation to the design of the tray" but instead be attributed "to intraoperative factors, primarily cementation technique." *Id.*

- ***Dr. Robinson***: From approximately 1995 to 2021, Dr. Robinson—another American Board of Orthopaedic Surgery-certified physician—implanted more than 3,000 Optetrak knees, including Finned, Trapezoidal, and Fit tibial trays. SF ¶ 19. He concluded that, "[b]ased on [his] own experience implanting Optetrak knees, [his] thorough knowledge of the literature regarding the Optetrak knee lineage, and [his] personal experience with the finned tibial design, there is no basis to believe that the [Device] has any design flaws or defects." *Id.*

- ***Dr. Gradisar***: Dr. Ivan Gradisar, whose surgical group implanted thousands of Devices, examined tibial loosening within his own group.

SF ¶ 33. He found that the rare instances of loosening involving Optetrak Finned Tibial Trays were a result of poor cementing technique, including (a) flexing the implant before the cement cures; (b) failing to seat the implant using constant pressure; (c) failing to keep the cement interfaces clean and dry; and (d) failing to prevent fat "blowback," which can cover the cement and compromise the bond. *Id.*

- ***Dr. Kim***: In an 11-year study using the finned fixed bearing modular tray and posterior stabilized design (which Relator Fuentes admits is the Device), Dr. Young-Hoo Kim and his colleagues found that not a single one of the study's 131 Optetrak knees experienced aseptic loosening. SF ¶ 35. The authors concluded that the Optetrak knee—with its 99% survival rate—"obtained favorable clinical and radiographic results," without a single instance of aseptic loosening. *Id.*

- ***Dr. Edwards***: Dr. John Edwards and his colleagues prepared a paper that was presented at American Academy of Orthopaedic Surgeons documenting one surgeon's 8.5-year experience with the Optetrak system. SF ¶ 36. That surgeon performed 1,526 surgeries using a near-even split of Finned and Trapezoid trays, with a reoperation rate of just 1.4% for any reason (not just aseptic loosening) and no reoperations to repair or replace the Device or for tibial-femoral instability. *Id.*

In addition to these surgeons' positive results with the Device, it is undisputed that cementation and alignment techniques are critical to successful TKAs, regardless of the manufacturer. SF ¶¶ 28, 30, 31. For example, in 2013 a team of physicians published a paper on the importance of medium-viscosity cement to promote cement penetration and the need for longer cement-cure time. SF ¶ 37. A similar study published in 2019 found "significantly higher" revision rates for surgeons using high-viscosity cement than those using low-viscosity cement. *Id.* Finally, misalignment of the prosthesis can result in increased instances of tibial loosening. *Id.*

In regard to Dr. Lemak's loosening issues, Dr. Petty made numerous attempts to assess his surgical problems, including offering to attend his surgeries or observing videos of his procedures. SF ¶ 32. Dr. Lemak refused. *Id.* Whenever a physician had a cluster of loosening—an extremely rare occurrence—Exactech made every effort to work with the surgeon to address the causes. SF ¶ 31. In all other cases, the surgeons' issues were resolved. *Id.* Had Dr. Lemak accepted that same offer, he likely would have all but eliminated his issues—just like Drs. McCloud and Moody.[20]

Given Exactech's reasonable belief that the Device was not defective, Relators cannot show, and no reasonable juror could find, that Exactech had knowledge that the Optetrak Finned Tibial Tray was defective.

2. Exactech developed the "Fit" tray as a natural evolution of the Optetrak knee system.

In August 2010, the FDA cleared Exactech's Logic Combination Tibial Tray, the "Fit" tray. SF ¶ 4. Relators allege that Exactech developed the Fit tray as a "silent recall" of the Device, allegedly because Exactech knew of the problem with the Device. *See* Am. Compl. ¶¶ 87–89. No evidence supports this allegation.

The Fit tray's development reflected a natural evolution of the Optetrak knee

[20] In connection with a separate lawsuit involving Dr. Lemak, Exactech obtained certain x-rays from Dr. Lemak's procedures, which Dr. Petty reviewed and observed that, like the other physicians who experienced loosening, Dr. Lemak was using incorrect cement technique. SF ¶ 32.

system by combining the best features of the Finned and Trapezoid Trays, eliminating the overhead associated with two separate trays. SF ¶ 5. Exactech did develop the Fit tray in a shorter timeframe compared to the Finned and Trapezoid Trays, but not as a result of any issues with the Finned Tray. *Id.* The timeframe stemmed primarily from two factors: (1) the Fit tray was a combination of the Finned and Trapezoid trays, which Exactech had manufactured successfully for twenty years; and (2) some of Exactech's competitors had already transitioned to a combination tray, creating market demand for Exactech do the same. SF ¶¶ 4–5.

The undisputed evidence shows that it was a business decision to develop the Fit tray. There is no admissible evidence to the contrary. Relators' timeline doesn't support their theory: there was no rush to develop a new product as a "silent recall"[21] when the Fit tray was FDA-cleared in August 2010, SF ¶¶ 4–5, seven years after Exactech learned of Dr. Moody's 2003 loosening issues. SF ¶ 31.

3. Exactech's decision to report, or not report, instances of tibial loosening to the FDA does not satisfy Relators' burden to prove knowledge.

Relators allege that Exactech failed to report certain premature tibial loosenings to the FDA, which they say shows that Exactech recklessly disregarded

[21] Exactech expects Relators will point to an academic discussion paper David Petty prepared for an executive leadership program assignment to describe a business problem. As background for the unrelated discussion that followed, the paper notes that Exactech developed the Fit tray on an accelerated timeline. That paper is inadmissible hearsay, and Relators failed to examine David Petty about it. Every witness that Relators did question about it testified that they disagreed that the characterization of the Fit tray development process in the paper. SF ¶ 5, 5 n.2.

its regulatory obligations. This allegation misses the mark on the facts and the law.

The FCA requires that a defendant "knowingly" violate the FCA, *see* 31 U.S.C. § 3729(a)(1), and defines knowingly as either "actual knowledge," "deliberate ignorance," or "reckless disregard." 31 U.S.C. § 3729(b)(1)(A). In *Safeco Insurance Company of America v. Burr*, the Supreme Court analyzed the Fair Credit Reporting Act's (FCRA) scienter provision, which contains a similar knowledge requirement to the FCA's. 551 U.S. 47, 70–71 (2007); *see also* 15 U.S.C. § 1681n(a) (FCRA requires a defendant to act "willfully"). The Court looked to the common-law meaning of willfully and determined that it covers both knowing and reckless violations of the statute. *Safeco*, 551 U.S. at 57–58. Even when a defendant incorrectly interprets a regulation, the defendant cannot act with reckless disregard if (1) the interpretation of the regulation was objectively reasonable so long as there is (2) no authoritative guidance cautioning defendants against the incorrect interpretation. *Id.* at 70–71. The Court also found the defendant's subjective intent irrelevant: the plaintiffs' argument that "evidence of subjective bad faith can support a willfulness finding even when the company's reading of the statute is objectively reasonable" is "unsound." *Id.* at 70–71 n.20.

Every single circuit court—including the Third, Fourth, Seventh, Eighth, Ninth, and D.C. Circuits—asked to apply *Safeco* to the FCA's scienter prong has done so. *See U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 356 (4th

Cir. 2022) (collecting caselaw). "[N]o circuit has held *Safeco* inapplicable to the FCA." *U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 466 (7th Cir. 2021) (rejecting dissent's argument that Eleventh Circuit declined to apply *Safeco* in *Phalp*). These holdings align with the well-established doctrine that the FCA is not concerned with run-of-the-mill regulatory violations. *Marsteller*, 880 F.3d at 1312; *Corsello*, 428 F.3d at 1012; *Roop*, 559 F.3d at 824–25 (a relator must show that the failure to comply with MDR regulations was material to the government's decision to pay a claim). Under the clear majority rule, absent authoritative contrary FDA guidance (there is none), Exactech is not liable unless no objectively reasonable reading of the regulations supports the alleged misrepresentations to the FDA.

Relators allege that Exactech had to report every instance of tibial loosening of which it was aware through an MDR or Adverse Event Report. SF ¶ 28 n.4 (Relator Farley explaining his understanding that trauma-induced revisions, such as a "car wreck" or "skiing accident," must be reported to the FDA). But that is not what the law requires. Instead, FDA's regulations require that, upon learning of a revision, Exactech must conduct an investigation and evaluate the cause. SF ¶¶ 28–29. If Exactech concluded that a device did not malfunction and that there was no device-related death or serious injury, it was not obligated to report that event. SF ¶ 29.

That's what happened. Following investigations into each report of tibial

loosening, Exactech determined that the cause was unrelated to the Device itself and instead caused by intraoperative factors. SF ¶¶ 28–30. Exactech concluded that no MDR or Adverse Event report was required. SF ¶ 28. This interpretation was correct. But even if it wasn't, it was "objectively reasonable." SF ¶ 29.

In fact, the FDA's guidance supports Exactech's interpretation. *Id.* The FDA explains in its 2016 guidance manual, "Medical Device Reporting for Manufacturers," that, if a medical-device manufacturer "determine[s] that an event is *solely the result of user error* with no other performance issue, and there has been *no device-related* death or serious injury, [the manufacturer is] not required to submit an MDR report . . . ."[22] The predecessor guidance from 1997 likewise supports Exactech's reasonable interpretation: if the failure is a result of surgical technique and not device-related, an MDR report is not required.[23]

Exactech determined the rare instances of loosening were "solely the result of user error" (cement and/or alignment technique), and there were no "device-related" injuries because the revisions resulted from intraoperative factors and surgical technique. SF ¶ 31. The Device did not fail, the injuries were not Device-related, and Exactech was "not required to submit an MDR report."[24] SF ¶¶ 28–30.

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[22] Medical Device Reporting for Manufacturers § 2.6 (Nov. 2016), *available at* https://www.fda.gov/media/86420/download (emphasis added).
[23] *See* Medical Device Reporting for Manufacturers 36 (March 1997), *available at* https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB99105421.xhtml.
[24] Citing 21 C.F.R. § 803.3(c), the Court found that improper cement technique likely qualifies as "user error," and thus, "Exactech is hard-pressed in arguing that its discoveries did not obligate it

As a matter of law, Exactech's interpretation of the regulation was objectively reasonable, precluding a finding of actual knowledge. Exactech could not have known it was acting wrongfully because its decision to not submit MDRs was supported by an objectively reasonable interpretation of the FDA regulations.

D. *Materiality*: Relators cannot satisfy the FCA's "rigorous" materiality standard.

The FCA's materiality element is "rigorous" and "demanding." *Escobar*, 579 U.S. at 192, 196 n.6. The relevant inquiry is whether a material misrepresentation would influence the government's decision to pay a claim. *U.S. ex rel. Matheny v. Medco Health Sols. Inc.*, 671 F.3d 1217, 1228 (11th Cir. 2012).

The Court found that Relators satisfied this demanding standard by pleading that, among other things, the Device failed "in over 3 out of 10 patients and at a rate ten times greater than the industry standard," and found it plausible the government would have attached special importance to such an extraordinary failure rate had it known. Order at 43.

Of course, Relators have since acknowledged they simply made up their alleged revision rate of 30–35%, SF ¶ 49, and the overwhelming evidence shows that the Device outperformed its competitors. SF ¶¶ 18–19. Exactech admits that Dr. Moody notified Exactech and others as early as 2003 (and discussed during

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to report to the FDA." Order at 31. Exactech disagrees with that conclusion, but presumably the Court based this conclusion on the now-baseless allegation of a 30–35% revision rate.

2005 and 2006 clinician meetings) that he had to revise a certain number of knees due to cementation problems, but Exactech was not required to submit MDR reports to the FDA for these loosenings. Indeed, Dr. Moody himself attributed the device failure to intraoperative factors. SF ¶ 31. Nor can Relators prove that Exactech's alleged "failure to submit MDR reports to the FDA was material to—that is, 'capable of influencing'—the government's decisions to pay countless unidentified Medicare reimbursement claims submitted by [Exactech] distributors" over the next 15 or so years. *Roop*, 559 F.3d at 824–25.

Perhaps the most compelling evidence that the government does not consider Relators' allegations material is that the government, having been made aware of those allegations since June 2018, has never withdrawn clearance for the Device. SF ¶ 12; *see U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010) (inferring lack of materiality when, after declining to intervene and being made aware of the allegations, the government "understood [the] potential risks, and decided to continue purchasing and using [the device] anyway").

In sum, Relators have no evidence that Exactech did not comply with FDA regulations, and no evidence that the alleged violations, if there were any, were material to the government's decision to pay for Device. Even if Exactech was required to report some of the revisions related to Drs. Hutchins or Moody (and it was not), those are only one-off issues. Congress did not intend for the FCA to

penalize companies for minor, regulatory violations, *see Escobar*, 579 U.S. at 194 ("Materiality ... cannot be found where noncompliance is minor or insubstantial."), especially where there is no evidence that the loosening issues were widespread. The Device, like all TKA devices, is a sophisticated medical device subject to a statistically predictable revision rate. *See Provuncher*, 2012 WL 3144885, at *1–2.

II. Relators' false-statement claim (Count III) fails because Relators have no evidence that Exactech knowingly made a materially false statement.

"To prove a claim under § 3729(a)(1)(B), a relator must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim." *Phalp*, 857 F.3d at 1154 (citing 31 U.S.C. § 3729(a)(1)(B)). For a statement to be deemed "false," the statement must "reflect an objective falsehood." *U.S. v. AseraCare, Inc.*, 938 F.3d 1278, 1296–97 (11th Cir. 2019). Relators cannot satisfy these elements.

A. Relators have no admissible evidence that Exactech knowingly made false statements.

The basis of Relators' third claim is that Exactech misrepresented the true revision rate of the Device. *See* Am. Compl. ¶ 212. As shown above, Relators' claim that the Device was defective is belied by its proven track record. Relators may disagree with Exactech's decision that additional MDR reports were not required, but that decision is objectively reasonable, so Exactech did not violate its reporting obligations as a matter of law. *Safeco*, 551 U.S. at 70–71.

Having failed to show that Exactech's stated revision rate is false, Relators cannot show that Exactech made any false statement, let alone knowingly made false statements. Relators' third count fails like the first two.

B. Relators have no evidence that the alleged false statements, if made, were material to the government's payment decision.

Relators also fail to show that the alleged false statement would have been material to the government's payment decision. Relators must show Exactech's alleged false statements influenced or "caused the government to actually pay a false claim." *Urquilla-Diaz*, 780 F.3d at 1052. They have no such evidence.

Relators allege that Exactech made false statements and omissions within 18 Adverse Event Reports it submitted to the FDA in 2008. Am. Compl. ¶¶ 102–05. There is no record evidence to support this. To the contrary, each Adverse Event report submitted by Exactech was accurate and complete to the best of Exactech's knowledge. SF ¶ 28. To satisfy their burden, Relators must point to specific false statements, and, of course, prove they are false. Relators have not done so. The Adverse Event reports allegedly containing false statements are not in the record. Relators never produced them in this case. Relators never asked a single deponent about these reports. And they certainly haven't established "who made" the false statement, "when the statement was made," or "what the defendants obtained as a result." *Matheny*, 671 F.3d at 1225. Even if Relators disagree with the content of the reports or Exactech's understanding that certain fields in the reports were not

required to be completed, the FCA is not the tool to address those minor regulatory errors. *See Escobar*, 579 U.S. at 194.

Relators also contend that Exactech intentionally made false or misleading statements in its marketing material, which caused the submission of a false claim. Am. Compl. ¶¶ 107, 123, 212. There is no competent evidence that Exactech made any material errors or misrepresentations in its marketing material. But even if Relators had this evidence, they have no evidence that the marketing material influenced the government's decision to pay a claim.

The materiality requirement is intended "to limit the scope of liability under the FCA to claims for which the government 'would have attached importance to the violation in determining whether to pay the claim.'" *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1300 (11th Cir. 2021) (quoting *Marsteller*, 880 F.3d at 1313). The Eleventh Circuit's materiality analysis is "holistic." *Id.* It has set forth a list of factors that are relevant to the materiality analysis, including (1) "whether the matter is an express condition to payment"; (2) "whether, to the extent the United States had actual knowledge of the misrepresentations, they had an effect on its behavior"; and (3) "whether the misrepresentations went to the essence of the bargain." *Id.* (citing *U.S. ex rel. Bibby v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1347 (11th Cir. 2021).

None of the materiality factors weigh in Relators' favor. First, the

government does not require a medical-device manufacturer to publish marketing material or sales brochures. Second, and most critically, Relators have no evidence that the government read or had knowledge of Exactech's brochures, so the brochures could not have had any effect on the government's decision to pay for the Device. And third, Exactech's marketing material was never negotiated with the government such that it had any impact on the bargain. Any alleged misrepresentations in Exactech's brochures or marketing material plainly could not be material to the government's payment decisions.

At best, Relators' issue with Exactech's marketing material is nothing more than a difference of opinion. And courts are clear on this point: "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ *cannot be false*." *U.S. v. AseraCare Inc*, 153 F. Supp. 3d 1372, 1383 (N.D. Ala. 2015); *see also U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) ("[E]xpressions of opinion or scientific judgments about which reasonable minds may differ cannot be 'false.'").

III. Relators have not established any of the elements to support their FCA-conspiracy claim (Count IV).

To prove their conspiracy claim, Relators must show "(1) an unlawful agreement between [the] defendants to commit a violation of [the FCA]; (2) an act performed in furtherance of the conspiracy; and (3) that the United States suffered damages as a result." *U.S. ex rel. Chase v. HPC Healthcare, Inc.*, 723 F. App'x

783, 791 (11th Cir. 2018) (citing *Corsello*, 428 F.3d at 1014). Relators must present evidence that "reasonably support[s] an inference that [the conspirators] shared [a] conspiratorial objective," *U.S. ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc.*, 597 F. Supp. 2d 1280, 1289 (M.D. Fla. 2009) (citing *U.S. ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 545–46 (7th Cir. 1999)), where they "intended 'to defraud the Government.'" *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008) (quoting 31 U.S.C. § 3729(a)(1)).

Relators allege that Exactech and Dr. Gradisar "entered a conspiratorial agreement to manipulate the outcome of Dr. Gradisar's [audit], in order to cover-up [sic] the defects of the" Device. Am. Compl. ¶¶ 73, 216–19. They then contend that Dr. Gradisar manipulated his data to "skew the results" of his audit to cover up the allegedly higher-than-reported revision rate. *Id.* ¶ 74; *see also id.* ¶¶ 75–79.[25]

To start with, because Exactech did not violate Sections §§ 3729(a)(1)(A), (B), or (G), as a matter of law, Exactech could not have conspired to violate those sections. *See U.S. ex rel. Marsteller v. Tilton*, No. 5:13-CV-00830-AKK, 2021 WL 3726605, at *17 (N.D. Ala. Aug. 23, 2021) ("Secondary liability for conspiracy [to

[25] The Court has found that Relators sufficiently alleged an FCA conspiracy claim because Exactech offered Dr. Lemak a consulting agreement after he communicated his tibial-loosening issues to Exactech. Order at 57. However, Relators did not allege a conspiracy with Dr. Lemak. Even if they had, Relators have no evidence of such a conspiracy. Exactech's single consulting agreement with Dr. Lemak fully complied with federal laws and regulations. SF ¶ 42. The facts also show that Dr. Lemak performed the work for which he was engaged, and he was paid fair-market value for his work. *See id.* Relators admit this much. *Id.*

violate the FCA] cannot exist without a viable underlying claim."). But even if Relators could show an underlying FCA violation (they cannot), Relators have no evidence to support their conspiracy claim. For Exactech and Dr. Gradisar to conspire, it requires a "meeting of the minds" to "defraud the Government." *U.S. ex rel. Holland v. DaVita, Inc.*, No. 617CV1592ORL37GJK, 2020 WL 12813696, at *4 (M.D. Fla. June 25, 2020). Relators have no such evidence. Relators did not depose Dr. Gradisar, and Relators' own testimony shows that Dr. Gradisar performed his audit for valid, lawful reasons. SF ¶¶ 33–34. Relator Fuentes testified that Exactech asked Dr. Gradisar to audit his experience implanting the Device because he maintained a personal registry dating back to 1994. SF ¶ 34. Relator Fuentes also testified that Dr. Gradisar was a "really good surgeon[]" whom he highly respects. SF ¶ 34; *id.* ("I respect Dr. Gradisar highly."). Given his knowledge of the Device and his personal registry, coupled with his reputation as a "really good surgeon," it is baffling that Relators allege Exactech had nefarious intent when it asked Dr. Gradisar to analyze the performance of the Device. *See id.* The audit clearly established that there was no issue with the Device. SF ¶ 33.

Good medical-device manufacturers continually seek to test their products. If a company could violate the FCA by performing such an audit, the FCA would serve as a perverse disincentive for companies to test and validate their products. This would run afoul of public policy and surely was not Congress's intent.

Finally, the government did not suffer damages as a result of the audit. Like the marketing brochures, Relators have no evidence that the government saw the audit or that it influenced the government's decision to pay a claim.

IV. Relators' redundant reverse-false-claim charge (Count V) fails for the same reasons as Counts I and II.

FCA liability under 31 U.S.C. § 3729(a)(1)(G) attaches when a defendant's conduct "results in no payment to the government when a payment is obligated." *U.S. ex rel. Bain v. Ga. Gulf Corp.*, 386 F.3d 648, 653 (5th Cir. 2004). Relators must show that Exactech "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ed] . . . an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). An obligation may result from the "retention of an overpayment" of Medicare funds. *See* 31 U.S.C. § 3729(b)(3); 42 U.S.C. § 1320a-7k(d)(4)(B).

The Court has acknowledged that this claim may be redundant to Relators' claims under §§ 3729(a)(1)(A) and (1)(B). *See* Order at 60–61; *see also U.S. ex rel. Schaengold v. Mem'l Health, Inc.*, No. 4:11-CV-58, 2014 WL 6908856, at *15–21 (S.D. Ga. Dec. 8, 2014).

And it is. The Court need look no further than Relators own responses to Exactech's discovery requests. Exactech asked for all documents and communications that support Counts I, II, and V. SF ¶ 56. Relators responded

identically for all three Counts: "[R]elators are producing all relevant documents in their possession responsive to this request. See documents bated RELATORS 000001-RELATORS000709. Discovery is ongoing and the relators reserve the right to supplement their responses as discovery progress." *Id.* Discovery has been closed for months, and Relators have never supplemented these responses.

Relators' reverse-false-claim count fails for at least three other reasons. First, Exactech is not a provider and does not submit claims or receive reimbursement, so Relators instead attempt to impose liability on Exactech by arguing that Exactech somehow caused the providers, specifically Dr. Lemak and Grandview Medical, to retain overpayments. But Relators cannot show that Dr. Lemak and Grandview Medical are obligated to return any funds to the government as a result of any false statements or records by Exactech, because they cannot show the existence of any false statements. *Supra* at 49–52. Second, Relators have no evidence that "Dr. Lemak and Grandview were reimbursed for false claims to Medicare and Medicaid." Order at 59. Thus, Exactech is left guessing as to what, if any, funds Dr. Lemak and Grandview Medical received.

V. There is no evidence that Exactech paid illegal remuneration to physicians in violation of the Anti-Kickback Statute (Count VI).

To prove their AKS claim, Relators must show that Exactech (1) knowingly and willfully, (2) offered or paid any remuneration to physicians, (3) to induce the physicians to use the Device, (4) in surgeries paid for by Medicare or Medicaid.

See U.S. v. Vernon, 723 F.3d 1234, 1252–53 (11th Cir. 2013) (citing 42 U.S.C. § 1320a–7b(b)(2)(A)). Relators have no proof to support this claim.

The Court pointed to only one alleged unlawful consulting agreement. *See* Order at 52–56. The Court found that Relators sufficiently pleaded that the purpose of Exactech's consulting payments with Dr. Lemak was to induce him to continue purchasing Exactech products. *Id.* at 53. But the evidence paints a very different picture: Exactech asked Relators to describe in "detail the factual knowledge [they] have to support" their allegation that any physician received an illegal consulting agreement. SF ¶ 61. Relators responded with identical, conclusory responses for all ten physicians they identified, including Dr. Lemak:

> Relator Dr. Fuentes has knowledge … based on his role as an Exactech surgeon liaison. … Relator Fuentes had access to documents, records, and other Exactech employees that identify the individuals with whom Exactech had consulting agreements.

Id. But Dr. Fuentes admitted in his deposition that this answer was "incorrect" because he did not know Dr. Lemak. SF ¶ 61.

Relator Wallace tried but failed to revive this claim in his deposition. His testimony instead makes clear that the consulting agreement was valid and legal. He admitted that Dr. Lemak was a "[g]reat candidate" for the sports-medicine design team. SF ¶ 63. He admitted that Dr. Lemak performed the work he was paid to do: working with Exactech to develop a "shoulder sports medicine line," and attending "several meetings." *Id.* He acknowledges that Exactech didn't pay Dr.

Lemak a consulting fee "to induce him to continue purchasing Exactech products." Order at 56. Instead, he was "100 billion percent" confident that Exactech decided to discontinue the shoulder project with Dr. Lemak because Dr. Lemak stopped using Exactech's knees. *Id.*[26] It is not a violation of the AKS, however, to not pay someone. If Relator Wallace's theory were true, Exactech's conduct could hardly induce or reward Dr. Lemak, as required under the AKS.

In any event, what actually happened is that, after meeting with Dr. Lemak on several occasions, Exactech learned that Dr. Lemak's hospital already exclusively carried a similar biologics product on its formulary and thus Dr. Lemak could not use Exactech's product and could not provide feedback or gather data. SF ¶42. Exactech paid Dr. Lemak fair-market compensation for the work he had performed ($5,400), including attending meetings and the time he billed to prepare for the meetings. *Id.* Dr. Lemak's consulting agreement was for a valid, lawful purpose, and one that Exactech publicly declared in accordance with the Physician Payments Sunshine Act. *See* Dr. Lemak's payments, *available at* https://openpaymentsdata.cms.gov/physician/863306 (last visited April 4, 2022).

[26] Relator Wallace's testimony follows a pattern of Relators' inconsistent responses to their discovery requests. *See* SF ¶¶ 61–63. He clearly had knowledge of Dr. Lemak's consulting agreement yet failed to supplement his answers to Exactech's interrogatories as required. *See* Fed. R. Civ. P. 26(e)(1)(A) (a party who "responded to an interrogatory ... must supplement [its] response … in a timely manner if the party learns that in some material respect the … response is incomplete or incorrect"). Exactech should not have to guess as to Relators' theory at this stage in the case.

With regard to the other nine physicians listed in Relator' interrogatory responses, SF ¶ 61, Relators appeared to abandon those claims at the motion-to-dismiss stage and should not be allowed to revive them now. Still, Relators' allegations are wholly conclusory and without any competent evidentiary support. Relator Fuentes even testified that "[he] never had access to … the real document and/or the needs assessment [for each consulting agreement] because that wasn't" his area of responsibility. SF ¶¶ 61–62. And for most of the surgeons Relator Fuentes listed, he essentially testified that it was just his hunch that the agreements were for improper purposes. *Id.* For others, such as Drs. Lemak and Slater, Relator Fuentes admitted he has no evidence to support these allegations. *Id.*

Finally, by the time Exactech considered engaging Dr. Lemak as a consultant, it had entered its DPA and CIA with the government. SF ¶¶ 41–42. Those agreements required Exactech to bolster its already strong compliance policies and procedures related to consulting arrangements, and an independent-review organization reviewed each agreement. SF ¶ 41. With these checks in place, a jury could not conclude that Exactech's consulting arrangements were improper.

VI. Even if Relators could produce evidence of claims that were false and material, which they cannot, the government was not damaged.

"The proper measure of the government's damages in an FCA action" like this is "the standard formulation for contract damages: the difference between what was promised and what was received." *U.S. ex rel. Harman v. Trinity Indus. Inc.*,

872 F.3d 645, 652–53 (5th Cir. 2017). But here, the government got precisely what it allegedly paid for: a safe and reliable TKR device. SF ¶ 18. There is no competent evidence that the Device was not necessary, or that the revision rate for the Device was higher than the industry standard. Relators have no evidence that the government suffered any damages in this case.[27]

Moreover, reimbursement amounts are based on invoices submitted to, and paid by, the MAC through the adjudication process. SF ¶ 27. Relators have provided no competent evidence that connects any such payment with Exactech, or demonstrates that Exactech-caused a claim to be submitted for reimbursement for a Device that actually failed. "Without a showing of *presentment*, there is no actionable damage under the FCA." *Clausen*, 290 F.3d at 1311. Thus, as a matter of law, Relators cannot show the government suffered any damages.

CONCLUSION

For the foregoing reasons, Exactech respectfully requests that the Court grant summary judgment in its favor and against Relators on all counts.

[27] Materiality and damages go hand-in-hand. *See Harman*, 872 at 652–53 ("[Relator's] failure to rebut the strong presumption against materiality also manifests in its effect on damages."). As shown above, Relators cannot satisfy the materiality standard. *Escobar*, 579 U.S. at 192, 196 n.6.

Respectfully submitted this 4th day of April, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of April, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notice of such filing to all attorneys of record.

/s/ Cory Wroblewski
Cory Wroblewski